UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NICHOLAS SKIADAS, *individually and on behalf of all others similarly situated*, Plaintiffs, -against- ACER THERAPEUTICS INC., CHRIS SCHELLING, and HARRY PALMIN, Defendants.	Case No. 1:19-CV-6137-GHW

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF'S MOTION FOR LEAVE TO FILE A THIRD AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Acer Therapeutics, Inc. ("Acer") is a small pharmaceutical company focused on developing life-saving treatments for rare diseases. This case is about Acer's multi-year effort to bring to market a drug called EDSIVO for treatment of vascular Ehlers-Danlos syndrome ("vEDS"), a rare, life-threatening disease for which there is currently no approved pharmacologic treatment. Acer submitted a New Drug Application ("NDA") for EDSIVO to the U.S. Food and Drug Administration ("FDA") based on a single clinical study (the "Ong Trial") that had shown positive results treating vEDS patients in Europe. The FDA denied the NDA, the stock dropped, and Plaintiff sued. Acer, together with individual defendants Chris Schelling and Harry Palmin ("Defendants"), remain hopeful that they can bring EDSIVO to vEDS patients who need it, and are developing a plan to support the potential resubmission of the NDA[1] as they continue to devote time, effort, and money toward this goal.

Plaintiff asks this Court to grant it leave to file a *fourth* version of the complaint in this case. But Plaintiff's proposed Third Amended Complaint ("TAC") comes after two rounds of motions to dismiss earlier complaints and, most importantly, nearly two months *after* the September 16 amendment deadline proposed by the parties and approved by the Court in its Case Management Order ("CMO" (ECF No. 67)). Rule 16 case management orders are meant to provide certainty to the parties and a management structure for the Court. Plaintiff provides no basis for ignoring the schedule, devoting only five of twenty-two pages in his opening brief to discussion of the legal issue this motion raises. That is presumably because the law requires Plaintiff to show good cause for amendment, which he cannot show. He waited nearly two months after receiving documents—that he knew he was getting—to seek amendment.

[1] *See* Acer's Nov. 10, 2020 Press Release, available at: https://www.acertx.com/2020/11/10/acer-therapeutics-reports-third-quarter-2020-financial-results-and-provides-corporate-update/.

Plaintiff should not be allowed to ignore the Court's Orders and amend the complaint because he gets a production with a document that he claims supports existing and new claims.

Plaintiff cannot establish good cause for another reason: the proposed amendments in the TAC include claims that are based on information that Plaintiff was aware or should have been aware of when the original complaint ("Original Complaint" (ECF No. 1)) was filed almost eighteen months ago. Plaintiff adds two categories of allegations in the TAC: (1) "new" claims that he had knowledge of when he filed previous versions of the Complaint, almost all of which were already dismissed or withdrawn (*see* Section I.A, *infra*); and (2) allegations that merely amplify his existing claim (*see* Section II.B, *infra*). Plaintiff cannot prove he was diligent in seeking amendment where he already had the underlying information and seeks to recycle claims from the Original Complaint and the First Amended Complaint ("FAC" (ECF No. 28)), which were subsequently withdrawn by Plaintiff in the FAC and Second Amended Complaint ("SAC" (ECF No. 43)) or dismissed by the Court on Defendants' motion to dismiss the SAC. These "new" claims also arise from non-actionable statements of corporate optimism or alleged omission of information that was already known to the market and will be the subject of a motion to dismiss if Plaintiff is granted leave to file the TAC. And amplified allegations regarding an existing claim do not support a late amendment. As the chart below illustrates, this motion is a textbook case of "enough is enough."

Category of Alleged Claims		Original Compl.	FAC	SAC	TAC
1.	The Ong Trial was "pivotal" or "statistically significant."	✓	✓	[**Withdrawn**]	✓[2]
2.	Acer's "product candidates are believed to present a comparatively de-risked profile . . ."	✓	[**Withdrawn**]		✓[2]
3.	May 2017 guidance on expected presentation of clinical data for NDA	✓	✓	✓ [**Dismissed**]	✓
4.	September 2015 FDA agreement regarding additional clinical development for NDA	✓	✓	✓ [**Survived MTD**]	✓[3]
5.	"Important phenotype characteristics" were "equally balanced" between celiprolol and the control groups in the Ong Trial				✓[3]

Finally, Plaintiff's TAC would unnecessarily delay the case—he already sought extension of the class certification pre-motion deadline because of it—and prejudice Defendants, because if leave is granted, the TAC will cause Defendants and the Court to expend additional resources responding to yet another complaint with a third motion to dismiss both new and resurrected claims. Plaintiff, on the other hand, would suffer no prejudice if leave to amend is denied because he is really seeking to add supposed evidence in his favor on the sole surviving claim in the SAC. As Plaintiff concedes, he added documents and some of the allegations to the

[2] As Defendants would brief in their motion to dismiss the TAC, if needed, the challenged statements in this category of the TAC are not actionable because they were expressions of corporate optimism.

[3] As Defendants would brief in their motion to dismiss the TAC, if needed, new allegations in the TAC that Defendants failed to disclose FDA communications would fail because the information communicated was already known to the market.

TAC as "definitive *proof* that Defendants statements that 'the FDA agreed that additional clinical development is not needed' . . . for EDSIVO were false and misleading." (Pltf.'s Mot. to Amend Br. ("Pltf.'s Br.") (ECF No. 85) at 1-2, 15-16 (emphasis added).) Not only is that assertion untrue, but amplification of existing claims is not a proper basis for amendment. Thus, the factors of prejudice and interest of justice, which the Court may consider on this motion, weigh in favor of denying Plaintiff's request to amend.

Plaintiff's motion to amend skirts the issue of good cause and diligence because Plaintiff cannot defend his disregard for the Court's schedule. Instead, Plaintiff's motion reads more like a trial brief than a pleading, while distorting Defendants' arguments and the record. And Plaintiff's merits assertions, in addition to not being at issue on this motion, purposefully miss the point. As explained in previous motions in this case, prior to the June 24, 2019 Complete Response Letter, the FDA did not tell Acer that it would not approve EDSIVO without an additional clinical trial and Defendants never stated the FDA had no concerns about the Ong Trial. To the contrary, the FDA accepted the NDA for filing with priority review, and the market knew full well of criticisms of the Ong Trial. Plaintiff makes much of an FDA statement in the September 2015 Meeting Minutes that "approval based solely on the published report of a single study is rare," but it was common knowledge that the FDA generally prefers two trials to demonstrate efficacy. And, most importantly, Acer never guaranteed that the NDA would be approved; its risk disclosures warned to the contrary, and the market knows that FDA approval is never certain. Defendants respectfully request that Plaintiff's late motion to amend the Complaint for a third time be denied.

PROCEDURAL HISTORY AND PLAINTIFF'S PROPOSED TAC

Plaintiff's TAC is an impermissible do-over. It represents the *fourth* version of the Complaint after two previous motions to dismiss and months after the Court-ordered deadline for amendments. As the chart above illustrates, the Original Complaint contained four categories of claims. Plaintiff dropped one to allege three categories in the FAC and then, rather than oppose Defendants' motion to dismiss, Plaintiff filed the SAC, this time with only two of the categories of claims. Defendants again moved to dismiss, and the Court granted Defendants' motion in part, leaving one category of claims remaining. Now, Plaintiff seeks to file the proposed TAC in an attempt to augment his existing claim and rewind the clock, adding back the categories of claims previously dismissed or withdrawn.

To provide more context, on July 1, 2019, the Original Complaint was filed on behalf of a putative class of stockholders who had purchased Acer stock between September 25, 2017, and June 24, 2019. The Original Complaint contained four categories of alleged misstatements: (1) statements from Acer's press releases dated September 25, 2017, and December 26, 2018, concerning the significance of the data from the supporting Ong Trial (Original Compl. ¶¶ 31-34, 41-42); (2) a statement in the 2018 10-K that Acer's drug candidates presented a "comparatively de-risked" profile (*id.* ¶ 46); (3) a statement in the 2017 10-K concerning a May 2017 FDA meeting (*id.* ¶ 36); and (4) a statement in the 2017 10-K concerning a September 2015 meeting with the FDA (*id.* ¶ 35).

Following his appointment as lead plaintiff, Plaintiff filed the FAC on December 3, 2019. In the FAC, Plaintiff *withdrew* the claim arising from the statement in the 2017 10-K that Acer's drug candidates presented a "comparatively de-risked" profile and raised instead the other three categories of alleged misstatements: (1) statements relating to the significance of the

Ong Trial data from Acer's press releases dated December 13, 2016, September 25, 2017, November 13, 2017, March 7, 2018, April 16, 2019, and May 14, 2019 (FAC ¶¶ 44, 78, 80, 82, 84, 88, 98-99, 102-03); (2) statements in the 2017 10-K and July 2018 Prospectus concerning a May 2017 FDA meeting (*id.* ¶¶ 92, 96); and (3) statements in the December 2017 Prospectus, 2017 10-K, and July 2018 Prospectus concerning a September 2015 meeting with the FDA (*id.* ¶¶ 86, 90, 94). After pre-motion letters and a Court conference, Defendants moved to dismiss the FAC on February 7, 2020.

Rather than opposing Defendants' motion to dismiss, Plaintiff filed a second amended complaint, the SAC, on February 28, 2020. In the SAC, Plaintiff withdrew allegations concerning Defendants' statements about the significance of the Ong Trial data and only asserted claims arising from Defendants' statements in the December 2017 Prospectus, 2017 10-K, and July 2018 Prospectus about the September 2015 and May 2017 FDA meetings. Plaintiff also alleged a class period from December 12, 2017 through June 24, 2019.

Defendants moved to dismiss the SAC on May 1, 2020. On June 16, 2020, the Court dismissed Plaintiff's claims concerning the May 2017 FDA meeting, finding that "No reasonable investor could interpret the statement that the FDA 'provided . . . guidance on the expected presentation of existing clinical data' to mean that the FDA had indicated that the Ong Trial data were adequate to assure FDA approval of EDSIVO." (Opinion & Order ("Op. & Order") (ECF No. 54) at 16-17.) The Court denied Defendants' motion as to Plaintiff's claims arising from the statements in the December 2017 Prospectus, 2017 10-K, and July 2018 Prospectus concerning the September 2015 FDA meeting. Defendants filed an Answer to the SAC on August 7, 2020, to the sole remaining claim.

On August 4, 2020, the parties met and conferred pursuant to Rule 26(f) and discussed scheduling a mediation for October. Plaintiff requested that Defendants produce meeting minutes, memoranda, and notes of FDA meetings, and other core FDA documents before the mediation. Defendants agreed to produce documents for the mediation by mid-September. Knowing those dates, Plaintiff himself proposed a case schedule that included the *September 16, 2020* deadline for amendments. The parties submitted that proposed case schedule to the Court on August 10, 2020, which provided more time for discovery than the Court's model form. (ECF No. 65.) At the August 17, 2020 Initial Pre-Trial Conference, this Court approved the schedule proposed by the parties, including the September 16 deadline. (*See* CMO at 2.) The Court also made clear that, "these deadlines, once I've established them, will be real deadlines. . . . If you choose not to do the work necessary to fully litigate the case because you hope that the case would settle, but it doesn't, you should not expect that I'll find that to be good cause for an extension of these deadlines which have been structured to permit the parties to focus on an early resolution of the case and are quite lengthy." (Aug. 17, 2020 Tr. at 10:16-17, 17:9-14.)

Defendants produced the agreed-upon documents for the mediation on September 11, 2020.[4] The parties submitted mediation briefs on September 30 and attended the mediation on October 7. The mediation was not successful.

[4] Plaintiff's counsel's statement that he "did not receive Defendant's production until Monday, September 14, 2020, after the Parties worked out some technical issues" is incorrect. (Pltf.'s Br. at 6 n.3; Decl. of Brian Alexander (ECF No. 86) ¶ 3.) Defendants sent the production to Plaintiff twice on September 11 around 7:37 p.m. and 11:56 p.m. On the morning of September 14, Plaintiff's counsel said he had not received it, but Defendants sent him the transmission confirmations and indicated the issue must be on Plaintiff's end. Without further involvement from Defendants, Plaintiff apparently worked out the issue, but the fact is the production was transmitted and available around 7:37 p.m. on September 11, 2020.

On Friday, November 6, at 9:34 p.m.—approximately two months after the mediation production—Plaintiff notified Defendants of his intention to move to amend and provided the proposed TAC. Then, around noon on Monday, November 9, Plaintiff informed Defendants that he intended to submit a letter notifying the Court of his intention to file a proposed TAC and gave Defendants until 4:30 p.m. that same day to propose redactions to his letter. Defendants provided proposed redactions the next day, November 10, and Plaintiff filed his letter. (ECF No. 72.)[5] Pursuant to Your Honor's Individual Rules of Practice, Defendants submitted a response letter on November 16. (ECF No. 74.) The Court held a Conference on November 25 and granted Plaintiff leave to file a motion to amend but directed the parties to brief the Rule 16 and timeliness arguments, not the futility arguments that would be preserved for a motion to dismiss, if any. (*See* Nov. 25, 2020 Tr. at 11:24-12:4 ("I expect that [Rule 16] will be the focus of the opposition and that it will not raise the issues of futility. Any challenges to the legal sufficiency of the complaint will come in another form of a motion to dismiss in the event that the Court grants leave to plaintiffs to file their proposed amended complaint.").) Despite this instruction, Plaintiff filed what is essentially a trial brief loaded with his one-sided version of the case.[6] Defendants maintain, as explained in their November 16 letter (ECF No. 74), that the proposed TAC fails to adequately state new claims, but, pursuant to the Court's direction, will

[5] Plaintiff argues Defendants somehow delayed his motion to amend by delaying their proposed redactions to the TAC exhibits. But Defendants provided the proposed redactions as soon as the Court granted leave to file the motion. *See* Section I.B, *infra*.

[6] Plaintiff misrepresents Defendants' arguments in their previous motions to dismiss, as discussed in more detail in Section III, *infra*. What Defendants argued was untenable was Plaintiff's assertion that Defendants proceeded with the NDA despite the FDA having allegedly told them that they would not approve EDSIVO without an additional clinical trial. Contrary to Plaintiff's assertion (Pltf.'s Br. at 20), Defendants never argued that the FDA did not raise any concerns about the NDA. Consistent with the Court's directive, however, Defendants will address this point fully in motion to dismiss briefing, if any.

fully brief a motion to dismiss if leave to amend again is granted and focus here instead on the Rule 16 issue before the Court.

Plaintiff's proposed TAC seeks to extend the start of the class period back to September 25, 2017, and add claims based on alleged statements or omissions—some of which were known to the market, some of which were corporate optimism, and some of which were previously dismissed by the Court or withdrawn by Plaintiff. Plaintiff's TAC contains five categories of claims: (1) the claim that Plaintiff previously withdrew from the FAC, arising from Defendants statements that the Ong Trial was, *inter alia*, "pivotal" and achieved "statistically significant" results (TAC ¶¶ 152, 155, 157, 161, 171, 173, 174, 184-85, 193-94, 196); (2) the claim that Plaintiff previously withdrew from the Original Complaint, arising from Defendants statement in the 2018 10-K that Acer's drug candidates had a "comparatively de-risked profile" (*id*. ¶ 188); (3) the claim that this Court previously dismissed, regarding Defendants statement about the FDA providing "additional guidance" at the May 2017 FDA meeting (*id*. ¶¶ 166, 179); (4) new assertions that Plaintiff alleges (and Defendants dispute) amplify the surviving claim regarding statements about the September 2015 FDA meeting (*id*. ¶¶ 160, 167, 180); and (5) a claim that Defendants' statement that "[i]mportant phenotype characteristics [were] equally balanced" in the Ong Trial was false or misleading (*id*. ¶¶ 156, 164, 172, 177, 190), which is based on publicly available information. (*See* Chart at p. 3, *supra*.)

ARGUMENT

Plaintiff's motion to file an inexcusably late and unnecessary third amended complaint should be denied. Despite the generally liberal standard of Rule 15(a), a court may deny leave to amend pleadings "where the moving party has failed to establish good cause, as required by Rule 16(b), to amend the pleadings after the deadline set in [a] scheduling order." *Kassner v.*

2nd Ave. Delicatessen Inc., 496 F.3d 229, 243 (2d Cir. 2007). By limiting the time for amendments, the rule is designed to offer a measure of certainty in pretrial proceedings, ensuring that "at some point both the parties and the pleadings will be fixed." *Id.* "The party moving to amend bears the burden of demonstrating good cause," *Int'l Techs. Mktg., Inc. v. Verint Sys., Ltd.*, No. 1:15-CV-2457-GHW, 2019 WL 1245013, at *3 (S.D.N.Y. Mar. 18, 2019). Here, Plaintiff fails to meet that burden. "[T]he primary consideration" to determine whether good cause exists "is whether the moving party can demonstrate diligence." *Kassner*, 496 F.3d at 244; *Holmes v. Grubman*, 568 F.3d 329, 335 (2d Cir. 2009). Plaintiff offers no good answer as to why the applicable deadline that he missed could not reasonably have been met with proper diligence. *Int'l Techs.*, 2019 WL 1245013 at *3. Plaintiff knew or should have known the information underlying the "new" allegations earlier—especially given that the majority of the "new" claims were previously raised in earlier versions of the Complaint.

In addition, leave to amend should be denied because the case will be delayed and Defendants will be prejudiced by the expenditure of time and resources responding to yet another complaint. In contrast, Plaintiff will not suffer any prejudice because, other than the improperly recycled claims, the substance of many of the proposed allegations merely amplify the surviving claim from Plaintiff's SAC. Finally, the interests of justice weigh against amendment; Plaintiff does not get to engage in multiple rounds of alleging, withdrawing, and pleading battles every time he receives a document he likes. Plaintiff misconstrues Defendants' arguments and the documents to argue, in vain, that the interests of justice support amendment.

I. PLAINTIFF OFFERS NO GOOD CAUSE FOR AN AMENDMENT NEARLY TWO MONTHS AFTER THE DEADLINE

Plaintiff missed (and never sought to extend) the Court-ordered deadline he proposed for amendments by nearly two months. And he himself had proposed that deadline aware of the

timing of the mediation and mediation production. Plaintiff cannot show any cause, let alone good cause, to upend the Court's schedule and cause Defendants and the Court to rewind the case and litigate yet another motion to dismiss. He should not be permitted now to amend the complaint, for a third time, based on a production of documents he knew would be made around the time of the deadline he proposed and never sought to extend. *See Morelli v. Alters*, No. 1:19-CV-10707-GHW, 2020 WL 6508858, at *3 (S.D.N.Y. Nov. 5, 2020) (denying amendment and noting that defendant failed to explain his delay in seeking amendment and failure to request an extension of the deadline).

A. Plaintiff Was Aware of the Facts as Seen in His Withdrawn or Dismissed Claims.

Plaintiff does not have a reasonable excuse for the nearly two-month delay in requesting leave to file the proposed TAC, because he was aware of the facts underlying his "new" claims (including those that were previously dismissed or withdrawn) well before September 16, 2020. The three previous versions of the complaint did not rely on any confidential witnesses or internal Acer documents; instead Plaintiff's claims were based on publicly available information. "A party is not diligent where the information motivating the request to file an amended complaint was previously available to the public." *Morelli*, 2020 WL 6508858, at *2. Plaintiff asserts he had to "*re-review[]* all of Defendants' *public statements* to determine if the new information rendered those statements false or misleading." (Pltf.'s Br. at 19 (emphasis added).) But a re-review of public statements does not justify ignoring the Court's schedule, particularly when the majority of Plaintiff's "new" claims were raised in previous versions of the complaint and were either withdrawn by Plaintiff or dismissed by the Court, including the following claims.

- Statistical Significance: Plaintiff's allegations in the TAC concerning the statistical significance of the Ong Trial were previously raised in the Original Complaint (Original Compl. ¶ 31), and the FAC asserted a claim arising from the same

September 2017 press release, among others, that included statements about the Ong Trial's statistical significance. (FAC ¶¶ 44, 78, 80, 82, 84, 88, 98-99, 102.) Importantly, Plaintiff *withdrew* those allegations when he omitted them from his SAC. In the TAC, Plaintiff includes ten additional statements concerning the statistical significance of the Ong Trial that were not included in previous versions of the complaint. (*See* TAC ¶¶ 155, 157, 171-74, 184-85, 193-94.) But those statements go to the same underlying alleged misstatement and in any event were publicly available and Plaintiff could have included—but failed to include—those statements in the FAC. Plaintiff's belated inclusion of these ten statements on a previously raised and withdrawn claim does not constitute good cause to allow a third amendment. *See Carnrite v. Granada Hosp. Grp., Inc.*, 175 F.R.D. 439, 448 (W.D.N.Y. 1997) (finding Plaintiff's counsel's "inadvertence" or oversight is not good cause for purposes of Rule 16(b) and denying amendment).

- De-Risked Profile: Similarly, the claim arising from Defendants' statement in the 2018 10-K that its drug candidates had a "de-risked" profile was previously included in the Original Complaint (Original Compl. ¶ 46), but Plaintiff chose not to include that claim in the FAC or SAC.

- Guidance: Plaintiff also reasserts his previously dismissed claim concerning Defendants statement about FDA "guidance" at the May 2017 FDA meeting. (TAC ¶¶ 167, 180.) Plaintiff alleged this exact claim in the SAC (SAC ¶¶ 110-11, 114-15), and the Court dismissed this claim on Defendants' motion to dismiss. (Op. & Order at 16-17.)

Plaintiff did not discover any of his "new" claims from information in the mediation production; rather, as the long history of amendments in this case makes clear, Plaintiff was aware or should have been aware of these claims and statements from the start of this case based on public information. He cannot misuse the mediation production to revive his withdrawn and dismissed claims. And, because he was already aware of these claims, he cannot argue that he exercised due diligence by waiting nearly two months after the deadline to seek to amend. *See Rent-A-Center, Inc. v. 47 Mamaroneck Ave. Corp.*, 215 F.R.D. 100, 104-05 (S.D.N.Y. 2003) (finding defendants lacked good cause to add counterclaim where the substance of the "new" claim was known when defendants filed their original amended answer). Similarly, as Defendants would more fully brief if necessary on a motion to dismiss, if leave to amend is granted, Plaintiff's claim concerning Defendants' statement about the patient "phenotype

characteristics" in the Ong Trial is based on publicly available information, as the Ong Trial was published in *The Lancet*.

In his moving brief, Plaintiff relies solely on cases that found the plaintiff diligent in moving to amend within three months of discovering *new* information. (Pltf.'s Br. at 19.) But even if Plaintiff had discovered the facts giving rise to the "new" claims in September, which the facts belie, the fact that Plaintiff sought amendment within three months does not *per se* demonstrate due diligence. Courts in this District, including this Court, have found that a movant was not diligent in bringing a motion to amend, despite moving within three months of learning new information, and have denied motions to amend. *See Morelli*, 2020 WL 6508858, at *3 (denying amendment due to movant's two and a half month delay in seeking amendment); *Gullo v. City of New York*, 540 F. App'x 45, 47 (2d Cir. 2013) (finding that the district court "acted well within its discretion" in concluding that plaintiff did not exercise due diligence after waiting three months to move for amendment after learning of information that formed the basis of the proposed amendment). Here, Plaintiff had access to information giving rise to the claims that were asserted or should have been asserted in the Original Complaint and FAC. And he had access to the mediation production in September but did not seek an extension or leave to amend the TAC until nearly two months later—this is not an exercise of diligence.

B. Defendants' Redactions to the TAC Exhibits Did Not Cause Plaintiff's Delay.

Plaintiff's assertions aside, Defendants are not responsible for his delay in bringing this motion. Two business days after providing Defendants a copy of the proposed TAC, Plaintiff filed a letter notifying the Court of his intention to move to amend. Defendants responded to Plaintiff's letter in the time provided by Your Honor's Individual Rules, and the Court set a Conference on Plaintiff's proposed motion. Because Plaintiff filed a pre-motion letter with the

Court (regardless of whether or not he believes he had to), he could not have filed a motion to amend before the Court's scheduled Conference on November 25. (*See* Nov. 23, 2020 Order (ECF No. 78) ("Plaintiff is directed not to file their amended complaint until after the conference").) Plaintiff's assertion, therefore, that his delay is somehow due to the time it took Defendants to provide proposed redactions for the exhibits to the motion to amend rings hollow. Defendants provided those redactions five days (including the Thanksgiving holiday weekend) after the Court granted Plaintiff leave to file this motion (despite Defendants' suggestion to Plaintiff that the filing could exclude such exhibits to avoid the need for redaction). The delay here is Plaintiff's choice, not Defendants' fault.

II. AMENDMENT WOULD PREJUDICE DEFENDANTS AND PLAINTIFF WOULD NOT SUFFER ANY PREJUDICE IF AMENDMENT IS DENIED

In determining what constitutes "prejudice," courts consider whether the assertion of the new claim would: (i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; or (ii) significantly delay the resolution of the dispute. *See Block v. First Blood Assocs*., 988 F.2d 344, 350 (2d Cir. 1993). Here, Plaintiff's proposed TAC does both as it upends the schedule and would require Defendants to brief another motion to dismiss. On the other hand, Plaintiff would not be prejudiced because he can use, if admissible, the facts alleged in his proposed TAC to pursue the claims asserted in the SAC.

A. Amendment Would Cause Defendants to Incur Additional Expenses and Unnecessarily Delay This Action.

The proposed TAC will delay—and already has delayed—the case schedule. Pursuant to the parties' August 10, 2020, joint scheduling letter to the Court, Plaintiff proposed that he would submit his pre-motion letter for class certification on November 23, 2020. (Joint Aug. 10, 2020 Ltr. (ECF No. 65) at 2.) Given the proposed TAC, and despite his claim that it would have no

effect on the schedule, Plaintiff requested, and this Court has granted, an extension of time for Plaintiff to file his motion for class certification until fourteen days after denial of Plaintiff's motion for leave to file the TAC or resolution of the motion to dismiss. (ECF Nos. 77, 80.) While "[m]ere delay . . . does not provide a basis for a district court to deny the right to amend," *Block,* 988 F.2d at 350, the delay, additional costs to Defendants in responding to the TAC, and Plaintiff's failure to demonstrate diligence weigh in favor of denying the motion to amend. *See Morelli*, 2020 WL 6508858, at *3 (denying motion to amend despite finding that prejudice to non-movant was not overwhelming).

If leave to amend is granted, Defendants will be prejudiced by the need to expend additional resources drafting another motion to dismiss and potentially a new answer. *See Morelli*, 2020 WL 6508858, at *3 (finding prejudice due to delay because new claims would likely require extensive motion practice to test the sufficiency of the new claims). In addition, a motion to dismiss will trigger a mandatory stay under the Private Securities Litigation Reform Act ("PSLRA") 15 U.S.C. § 78u–4(b)(3)(B) ("In any private action arising under this chapter, all discovery and other proceedings shall be stayed during the pendency of any motion to dismiss"). Courts in this District have found that the PSLRA stay is mandatory for all motions to dismiss. *See In re Smith Barney Transfer Agent Litig.*, No. 05 Civ. 7583, 2012 WL 1438241, at *2 (S.D.N.Y. Apr. 25, 2012) (finding "discovery must be stayed pending all motions to dismiss, even if an earlier motion to dismiss failed."); *see also Cartica Mgmt., LLC v. CorpBanca S.A.*, No. 14-CV-2258 (PKC), 2014 WL 12788656, at *1 (S.D.N.Y. Aug. 1, 2014).[7] And, the scope of

[7] At the November 25 conference, Plaintiff cited *In re Salomon Analyst Litig.*, 373 F. Supp. 2d 252 (S.D.N.Y. 2005) to argue that the Court has discretion to apply a stay of discovery under the PSLRA to a successive motion to dismiss. Plaintiff does not cite to any case law in his brief regarding the PSLRA stay, however, likely because he had previously relied on dicta in *Salomon*. *See In re Salomon*, 373 F. Supp. 2d at 256 (discussing whether the PSLRA stay was automatic but ultimately *holding* that the successive motion to dismiss resulted in stay of discovery under PSLRA). In any event, the court in *In re Smith Barney*, which was decided after *Salomon* and assessed the

discovery is unsettled because Plaintiff seeks to file a late TAC with additional allegations about additional statements and an expanded class period. Indeed, in his motion to extend time for class certification briefing, Plaintiff acknowledged that he "believes that the Court should defer Plaintiff's motion for class certification until the Court determines the operative class period." (Pltf.'s Nov. 19, 2020 Ltr. (ECF No. 77) at 1.)

B. Plaintiff Would Not Suffer Any Prejudice if the Motion Is Denied.

As set forth above, Plaintiff should not be permitted to revive claims already withdrawn or dismissed, and so he would not be prejudiced by a denial that forecloses what he can no longer claim. As for the additional allegations concededly added as "proof" of the claim that survived the motion to dismiss the SAC (Pltf.'s Br. at 1-2, 15-16), courts have denied motions to amend "to amplify facts" where such amendment does not "affect the claims to be tried," is "unnecessary" and would "needlessly [ ] require the defendant to expend time and resources drafting an answer." *Joint Stock Co. Channel One Russia Worldwide v. Infomir LLC,* No. 16-CV-1318 (GBD) (BCM), 2020 WL 1659849, at *13 (S.D.N.Y. Apr. 3, 2020) (collecting cases). Not only does the proposed TAC not prove Plaintiff's claim (the record from Acer's multi-year interactions with the FDA regarding the NDA clearly shows that the FDA did not tell Acer that it would not approve EDSIVO without an additional clinical trial), these additional allegations are not a proper reason for amendment, particularly a late one.

Plaintiff alleged in the SAC that Defendants misrepresented the likelihood of FDA approval by stating the FDA "agreed" at the September 2015 that no further clinical development was needed for approval. Defendants, of course, deny that claim, and continue to assert that the

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weight of authority, found that the PSLRA stay is unambiguously mandatory and automatically applies to *any* motion to dismiss. *See In re Smith Barney*, 2012 WL 1438241 at *2 ("there is nothing ambiguous about the meaning of 'any'" motion to dismiss in the plain language of the PSLRA's stay provision).

statement pertained to submission, not approval, of the NDA, but in any event, as Plaintiff acknowledges, the Court has already held it was sufficiently pled. (Pltf.'s Br. at 2.) Plaintiff does not need to amend the complaint, upend the schedule, and cause Defendants and the Court to expend resources on another motion to dismiss to add proof at the pleading stage. Nor is it required that Plaintiff attach the confidential communications between Acer and the FDA as exhibits to the TAC or directly quote from documents, as the Court noted at the November 25 Conference. (*See* Nov. 25, 2020 Tr. at 13:16-23.) Plaintiff's motion itself shows that there is no prejudice from denial of an amendment that includes additional facts for a claim the Court already found Plaintiff sufficiently asserted in the SAC. (*See* Pltf.'s Br. at 20 ("the new allegations are closely related to the allegations in the Second Amended Complaint—both are based on the FDA's communications with Acer about the Ong Trial and EDSIVO's NDA.").)

III. THE INTERESTS OF JUSTICE WOULD NOT BE SERVED BY ALLOWING AMENDMENT

The interests of justice would not be served by allowing Plaintiff to file an untimely complaint to recycle previously dismissed or withdrawn claims and add facts that amplify his existing claim. Plaintiff has already amended the Complaint twice, and Defendants have already filed two motions to dismiss. The interests of justice especially do not weigh in favor of amendment, with its delays and costs, for a small pharmaceutical company. (*See* Aug. 17, 2020 Tr. at 9:18-10:15 (discussion of the parties' effort to seek an early resolution of the case to conserve resources).) Acer has only 20 employees and a total market capitalization of approximately $30 million and is still working to develop four separate drugs addressing serious unmet medical needs. Rather than promote the efficient resolution of this matter, Plaintiff's proposed TAC will burden Defendants with additional costs and delay, providing further reason to deny the motion.

Furthermore, Plaintiff misconstrues Defendants' arguments on their motion to dismiss the SAC and twists the facts in order to argue that "justice requires that the Court grant Plaintiff's leave to amend." (Pltf.'s Br. at 21-22.) In their motion to dismiss the SAC, Defendants argued that Plaintiff's theory—that the FDA had told Acer that it could not submit the NDA or that the FDA would not approve EDSIVO without an additional clinical trial—was untenable and implausible. (Defs.' Mot. to Dismiss Br. (ECF No. 50) at 19.) The Court acknowledged that Defendants' argument has "some bite," but found that Plaintiff alleged another plausible theory. (Op. & Order at 22.) Contrary to Plaintiff's assertion otherwise, Defendants never represented that "the suggestion that Acer would have moved forward with its NDA for EDSIVO even after the FDA criticized the Ong Trial [w]as 'implausible to the point of absurdity.'" (Pltf.'s Br. at 3.) Defendants never represented that the FDA did not have or did not express concerns about the NDA. Defendants' argument was that it was implausible Acer would have moved forward if the FDA told them it would not approve EDSIVO without an additional clinical trial. That argument is clearly stated in the portion of Defendants' prior motion to dismiss brief that Plaintiff relies on—"By this Plaintiff *suggests that the FDA would have told Defendants that it would* not *approve* the NDA for EDSIVO without further clinical study." (Pltf.'s Br. at 4; Defs.' Mot. to Dismiss Br. at 19 (emphasis added).)

Plaintiff similarly misconstrues the FDA documents produced by Defendants. The documents set forth an extensive, several-year record of communications and meetings between Acer and the FDA concerning the NDA. Although the FDA expressed some concerns about the Ong Trial, the documents show that Defendants worked with the FDA and submitted additional information and documents in response to the FDA's requests. Contrary to Plaintiff's interpretation, the record does not establish that the FDA communicated to Acer that it would not

approve the NDA based on the Ong Trial. The FDA simply said that it would not *commit in advance* to approval, reserving several issues for substantive review following acceptance for filing of the NDA. If, as Plaintiff alleges, the FDA communicated to Acer as early as May 2017 that issues with the Ong Trial were insurmountable and it would not approve EDSIVO without an additional study, the FDA's subsequent actions—telling Acer to schedule future meetings concerning the NDA, requesting additional documents and information concerning the Ong Trial, advising Acer regarding the presentation of the Ong Trial data and Acer's analysis in the NDA, ***accepting*** the NDA for filing, granting priority review, and describing possible paths forward that could provide the substantial evidence of effectiveness needed to support the potential resubmission of the NDA[8]—would indeed defy logic. The fact is, the Ong Trial data and criticisms thereof were publicly available, the public was aware that Acer was relying on the Ong Trial alone to support its NDA, and it was common knowledge that the FDA generally prefers two trials to demonstrate efficacy. And Acer repeatedly warned investors that approval was not guaranteed. Plaintiff's twisting of the facts does not tip the balance in favor of amendment.

CONCLUSION

Defendants respectfully request that the Court deny Plaintiff's motion for leave to file the proposed TAC.

[8] *See* Acer's Mar. 18, 2020 Press Release, available at: https://www.acertx.com/2020/03/18/acer-receives-formal-dispute-resolution-request-fdrr-response-from-fdas-office-of-new-drugs/.

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